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Pfizer Announces Results from XELJANZ® (tofacitinib citrate) ORAL Strategy Study Published in The Lancet and Presented at the EULAR Annual Congress

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ORAL Strategy is the First Trial to Compare a JAK Inhibitor, XELJANZ, as Monotherapy or in Combination with Methotrexate (MTX) versus Humira® (adalimumab) plus MTX

“Differences in ACR50 Response Rate at Month 6.”

Pfizer Inc. (NYSE:PFE) announced today detailed results from ORAL Strategy, a head-to-head, noninferiority Phase 3b/4 study of XELJANZ® (tofacitinib citrate) 5 mg twice daily (BID) as monotherapy or in combination with methotrexate (MTX) compared to Humira® plus MTX in the treatment of moderate to severe rheumatoid arthritis (RA). ORAL Strategy also compared XELJANZ monotherapy to XELJANZ in combination with MTX. The study results were published online in The Lancet and will be presented during an oral session at the EULAR Annual European Congress of Rheumatology in Madrid, Spain (16 June).

“Our extensive RA clinical development program has demonstrated the overall efficacy and safety of XELJANZ with or without methotrexate in patients living with moderate to severe RA. ORAL Strategy is a bold study that directly compared XELJANZ as a monotherapy or in combination with methotrexate to Humira in combination with methotrexate,” said Michael Corbo, Chief Development Officer, Inflammation & Immunology, Pfizer Global Product Development. “The totality of the ORAL Strategy results add to body of evidence for XELJANZ and further demonstrates Pfizer’s commitment to putting patients first by helping physicians make informed treatment decisions.”

Efficacy Results

The percentage of patients achieving an ACR50 response at Month 6, the primary efficacy endpoint, for each arm include:

XELJANZ 5 mg BID plus MTX: 46.0% (n=173)
XELJANZ 5 mg BID monotherapy: 38.3% (n=147)
Humira 40 mg every other week (EOW) plus MTX: 43.8% (n=169)
Refer to data plot showing “Differences in ACR50 Response Rate at Month 6.”

“As expected, XELJANZ in combination with methotrexate provided similar ACR50 response rates to Humira plus methotrexate,” said Dr. Roy Fleischmann, study author and clinical professor in the Department of Internal Medicine at the University of Texas Southwestern Medical Center and Co-Medical Director, Metroplex Clinical

Research Center. “Although XELJANZ monotherapy did not demonstrate noninferiority to either combination arm, the clinical responses observed are reflective of those in the Phase 3 clinical program and affirm our understanding that XELJANZ is an important option both in combination with MTX and as monotherapy for patients who do not respond to or are intolerant to methotrexate.”

Safety Results

The safety findings in ORAL Strategy were consistent with the known adverse events (AEs) profile for XELJANZ. The most frequently reported AEs for each study group were upper respiratory tract infections, alanine aminotransferase elevation, nasopharyngitis, urinary tract infections and nausea. Overall AEs rates were comparable between treatment arms; the majority of AEs were mild to moderate in severity. Rates of serious AEs (SAEs) and discontinuations due to AEs were generally similar between treatment arms. Over the course of the study, the following percentages of patients experienced AEs and serious AEs across treatment groups:

AEs

XELJANZ 5 mg BID plus MTX: 61.4% (n= 231)
XELJANZ 5 mg BID monotherapy: 58.9% (n=226)
Humira 40 mg EOW plus MTX: 65.5% (n= 253)
SAEs

XELJANZ 5 mg BID plus MTX: 7.2% (n=27)
XELJANZ 5 mg BID monotherapy: 9.1% (n=35)
Humira 40 mg EOW plus MTX: 6.2% (n=24)
Top-line results for ORAL Strategy were announced in February 2017.

About Rheumatoid Arthritis (RA)

RA is a chronic, inflammatory autoimmune disease that affects approximately 17.6 million people worldwide and 1.6 million people in the U.S. It causes a range of symptoms, including pain and swelling in the joints, particularly those in the hands, feet and knees, which may lead to joint damage and eventual disability. RA can be treated with various types of medications, including steroids, conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) and biologic disease-modifying antirheumatic drugs (bDMARDs). Many physicians use combination therapy with MTX when treating patients with moderate to severe RA. However, some patients discontinue their MTX, which may result in reduced efficacy of these treatments regimens.

About XELJANZ (tofacitinib citrate) and XELJANZ XR (tofacitinib citrate) extended-release

XELJANZ®/XELJANZ XR® (tofacitinib citrate) is a prescription medicine called a Janus kinase (JAK) inhibitor. XELJANZ is approved in more than 80 countries around the world for the treatment of moderately to severely active rheumatoid arthritis (RA). Since it was first approved in the United States in 2012, XELJANZ has been prescribed to more than 90,000 patients worldwide. XELJANZ XR is the first once-daily oral JAK inhibitor approved for the treatment of moderately to severely active RA in eight countries around the world.

XELJANZ/XELJANZ XR U.S. Label Information

XELJANZ (tofacitinib citrate)/XELJANZ XR (tofacitinib citrate) is a prescription medicine called a Janus kinase (JAK) inhibitor. XELJANZ/XELJANZ XR is used to treat adults with moderately to severely active rheumatoid arthritis in which methotrexate did not work well. XELJANZ/XELJANZ XR may be used as a single agent or in combination with methotrexate (MTX) or other non-biologic disease-modifying antirheumatic drugs

(DMARDs). Use of XELJANZ/XELJANZ XR in combination with biologic DMARDs or potent immunosuppressants, such as azathioprine and cyclosporine, is not recommended.

It is not known if XELJANZ/XELJANZ XR is safe and effective in people with hepatitis B or C.
XELJANZ/XELJANZ XR is not for people with severe liver problems.
It is not known if XELJANZ/XELJANZ XR is safe and effective in children.

Important Safety Information

XELJANZ/XELJANZ XR can lower the ability of the immune system to fight infections. Some people can have serious infections while taking XELJANZ/XELJANZ XR, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections. Healthcare providers should test patients for TB before starting XELJANZ/XELJANZ XR, and monitor them closely for signs and symptoms of TB and other infections during treatment. People should not start taking XELJANZ/XELJANZ XR if they have any kind of infection unless their healthcare provider tells them it is okay.
People may be at a higher risk of developing shingles.
XELJANZ/XELJANZ XR may increase the risk of certain cancers by changing the way the immune system works. Lymphoma and other cancers, including skin cancers, can happen in patients taking XELJANZ/XELJANZ XR.
The risks and benefits of treatment should be considered prior to initiating XELJANZ/XELJANZ XR in patients with chronic or recurrent infection; who have been exposed to tuberculosis; with a history of a serious or an opportunistic infection; who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or with underlying conditions that may predispose them to infection.
Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), was observed in clinical studies with XELJANZ.
Use of live vaccines should be avoided concurrently with XELJANZ/XELJANZ XR. Update immunizations in agreement with current immunization guidelines prior to initiating XELJANZ/XELJANZ XR therapy.
Some people who have taken XELJANZ with certain other medicines to prevent kidney transplant rejection have had a problem with certain white blood cells growing out of control (Epstein Barr virus-associated post-transplant lymphoproliferative disorder).
Some people taking XELJANZ/XELJANZ XR can get tears in their stomach or intestines. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. XELJANZ/XELJANZ XR should be used with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis), or who have a narrowing within their digestive tract. Patients should tell their healthcare provider right away if they have fever and stomach-area pain that does not go away or a change in bowel habits.
XELJANZ/XELJANZ XR can cause changes in certain lab test results including low blood cell counts, increases in certain liver tests, and increases in cholesterol levels. Healthcare providers should do blood tests before starting patients on XELJANZ/XELJANZ XR and while they are taking XELJANZ/XELJANZ XR, to check for these side effects. Normal cholesterol levels are important to good heart health. Healthcare providers may stop XELJANZ/XELJANZ XR treatment because of changes in blood cell counts or liver test results.
Use of XELJANZ/XELJANZ XR in patients with severe hepatic impairment is not recommended.
Patients should tell their healthcare providers if they plan to become pregnant or are pregnant.
It is not known if XELJANZ/XELJANZ XR will harm an unborn baby. To monitor the outcomes of pregnant women exposed to XELJANZ/XELJANZ XR, a registry has been established. Physicians are encouraged to register patients and pregnant women are encouraged to register themselves by calling 1-877-311-8972.

Patients should tell their healthcare providers if they plan to breastfeed or are breastfeeding. Patients and their healthcare provider should decide if they will take XELJANZ/XELJANZ XR or breastfeed. They should not do both.
In carriers of the hepatitis B or C virus (viruses that affect the liver), the virus may become active while using XELJANZ/XELJANZ XR. Healthcare providers may do blood tests before and during treatment with XELJANZ/XELJANZ XR.
Common side effects include upper respiratory tract infections (common cold, sinus infections), headache, diarrhea, and nasal congestion, sore throat, and runny nose (nasopharyngitis).
Please click the direct link to the full US Prescribing Information for XELJANZ/XELJANZ XR, including Boxed Warning and Medication Guide: http://labeling.pfizer.com/ShowLabeling.aspx?id=959.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.pfizer.com. In addition, to learn more, please visit us on www.pfizer.com and follow us on Twitter at @Pfizer and @PfizerNews, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

DISCLOSURE NOTICE: The information contained in this release is as of June 16, 2017. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about XELJANZ (tofacitinib citrate) that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including, without limitation, the ability to meet anticipated trial commencement and completion dates and regulatory submission dates, as well as the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; uncertainties regarding the commercial success of XELJANZ and XELJANZ XR; uncertainties regarding the commercial impact of the results of the ORAL Strategy trial; whether and when any other applications for XELJANZ or XELJANZ XR may be filed with regulatory authorities in any jurisdictions; whether and when regulatory authorities in any jurisdictions may approve any such applications and/or any other applications that are pending or may be filed for XELJANZ or XELJANZ XR, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of XELJANZ and XELJANZ XR; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer’s Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned “Risk Factors” and “Forward-Looking Information and Factors That May Affect Future Results”, as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

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